4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0055]

Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry; Extension of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment periods.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment periods for the Draft Guidance entitled, "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods" that appeared in the Federal Register of June 2, 2016. In the notice, we requested comments on developing the sodium targets and for implementation of the guidance document. We are taking this action in response to requests to extend the two comment periods to allow interested persons additional time to submit comments.

DATES: We are extending the comment periods on the draft guidance published June 2, 2016 (81 FR 35363). Submit either electronic or written comments on Issues 1 through 4 in section IV of the notice of availability that published on June 2, 2016, by October 17, 2016. Submit either electronic or written comments on Issues 5 through 8 in section IV of the notice of availability that published on June 2, 2016, by December 2, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-0055 for "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kasey Heintz, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1376.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 2, 2016 (81 FR 35363), we published a notice announcing the availability of a draft guidance entitled, "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods." Section IV of the notice, "Issues for Consideration," listed eight specific questions (or "issues") and provided two comment periods for the submission of comments pertaining to these issues (81 FR 35363 at 35366). The comment period for Issues related primarily to short-term goals (Issues 1 through 4) was scheduled to end on August 31, 2016, and the comment period for issues related primarily to long-term goals (Issues 5 through 8) was scheduled to end on October 31, 2016. Comments on Issues 1 through 8 will inform our final guidance on the voluntary sodium reduction goals.

We received requests for 90- and 30-day extensions of these comment periods, respectively. In general, the requests expressed concern that the current 90- and 150-day comment periods do not allow sufficient time to develop a meaningful or thoughtful response to

the draft guidance. Some requests mentioned a need for companies to review the sodium concentration in their products, to consider what technology might be needed to meet the sodium reduction goals, and to address FDA requirements. The requested extensions would result in a 180-day comment period for all eight Issues for Consideration. We also received comments opposed to any extensions of the comment period related to the short-term goals. These comments expressed their view that the initial comment period provided sufficient time for stakeholders to review the draft guidance and to contribute informed comments and that it is important for FDA to move forward in finalizing the short-term goals for public health reasons.

We considered the requests and are extending the comment periods for the draft guidance as follows: For Issues 1 through 4, we are extending the comment period until October 17, 2016, and for Issues 5 through 8 we are extending the comment period until December 2, 2016. We believe that these extensions allow adequate time for interested persons to submit comments without significantly delaying finalizing the guidance.

Dated: August 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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